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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,810

09/20/2005

Vernon L. Alvarez

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

02/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,810	Applicant(s) ALVAREZ ET AL.	
	Examiner DAVID LUKTON	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 42-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In response to the previous restriction (mailed 1/24/08), applicants have cancelled all claims and added claims 42-49. Claims 42-49 are now pending.

As a result of the new claims, a second restriction requirement is now imposed. First, however, the following subgenera are defined:

G1: This subgenus is limited to a method of altering the course of a biochemical process, either *in vivo* or *in vitro*; included would be a method of inhibiting proliferation of tumor cells;

G2: this subgenus is limited to a method of treating a disease in a host or otherwise improving the health of the host; treatment of cancer would be included in this subgenus;

G3: this subgenus is limited to diagnostic assays, such as (i) determining the extent to which a peptide, or series of peptides can alter the course of a biochemical process or (ii) determining the extent to which a peptide or series of peptides can bind to another physical entity;

G4: This subgenus includes any embodiment encompassed by claim 42, with the proviso the G1, G2 and G3 are excluded.

. . . .

Restriction to one of the following inventions is required under 35 U.S.C. §121 (the numbering begins with 14, in order to avoid conflict with the previous numbering system):

14) Claims 42-49, drawn to a method, limited to G1.

15) Claims 42-49, drawn to a method, limited to G2.

16) Claims 42-49, drawn to a method, limited to G3.

17) Claims 42-49, drawn to a method, limited to G4.

The claimed inventions are distinct.

Groups 14 and 15 are distinct. It may be the case that the peptides are known for treating certain diseases, but the mechanism by which this has been previously reported is different from that asserted by applicants.

Group 16 is distinct from Groups 14 and 15; group 16 is a diagnostic assay, whereas Group 15 is a therapeutic method, and Group 14 is drawn to a method of inhibiting or augmenting the course of a given biochemical process.

Group 17 is probably a “null” group, i.e., there are probably no embodiments that would fall within the scope of this. In the event that applicants agree with this conclusion, applicants can simply elect one of the other three groups.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

Art Unit: 1654

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect species/ subgenera (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable:

- a) a specific cell type;
- b) one of the following: (i) the elected polypeptide is linked to a cytotoxic agent, but is not labeled; (ii) the elected polypeptide is labeled but is not linked to a cytotoxic agent; (iii) the elected polypeptide is labeled and is also linked to a cytotoxic agent; or (iv) the elected polypeptide is neither labeled nor linked to a cytotoxic agent;
- c) a specific and fully defined polypeptide in which all amino acids are accounted for and all other substituents (if any) are also accounted for.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654